

Assess the reporting quality of RCTs of treatments in non-hodgkin's lymphoma using the CONSORT statement from 2011 to 2016.

Αξιολόγηση της ποιότητας των αναφορών σε μελέτες RCTs για την θεραπεία του non-hodgkin's λεμφώματος με τη χρήση του CONSORT statement από το 2011 έως το 2016.

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**ΜΕΘΟΔΟΛΟΓΙΑ ΒΙΟΪΑΤΡΙΚΗΣ ΕΡΕΥΝΑΣ, ΒΙΟΣΤΑΤΙΣΤΙΚΗ
ΚΑΙ ΚΛΙΝΙΚΗ ΒΙΟΠΛΗΡΟΦΟΡΙΚΗ**

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ABSTRACT

Randomized Control Trial (RCT) is considered the most accurate method in evaluating the effectiveness of a treatment. In 1996, in order to improve the quality of published studies, the Consolidated Standards for Reporting Trials (CONSORT) statement was published. It was the result of a cooperation of scientists and publishers aiming to provide authors a guideline.

I searched Pub Med database for RCTs published from 2011 to 2016, for treatment on Non-Hodgkin's lymphoma (NHL). From the 183 studies found in Pub Med, eligible for further analysis were 74. Based on the evaluation the compliance with the CONSORT statement remains very low. Authors still avoid reporting important details about the design of their trials, such as randomization strategy, the calculation of the sample size etc.

1. **INTRODUCTION**

Randomized Control Trials (RCTs) are considered the gold standard in scientific research and the most accurate methods to determine if there is a cause-effect relation between treatment and outcome as well as the efficacy of the treatment (Kober *et al.*, 2006). Participants are randomly assigned to either a control group (placebo or standard method of treatment) or to one of the experimental groups. Randomization process of patients without intervention of researchers minimizes selection bias. Therefore, on average the characteristics of the participants will be similar among the different groups without affecting the results. A well designed and executed RCT can result to more reliable and transparent evidence. Over the last decades, RCTs publications have overrun biomedical journals and the need for an evaluation guideline arose.

On 1996, a group of scientists and editors published the CONSORT (Consolidated Standards of Reporting Trials) statement aiming to help authors improve the reporting quality of RCTs reports. CONSORT statement was revised again on 2001 and 2010 in light of new empirical evidence and experience. The use of CONSORT statement is associated with the improvement of the reporting quality of RCTs (Schulz *et al.* 2010) However, according to similar evaluation research the compliance of RCTs with the CONSORT statement has increased but still there is no great improvement (Ziogas-Zintzaras 2009, Kober *et al.* 2006).

Non-Hodgkin's Lymphoma (NHL) is the most common cancer of lymphatic system, a part of the immune system. It consists of a group of several closely related cancers. The World Health Organization (WHO) estimates that there are 61 distinct types of NHL. NHL can be divided in two major groups:

- B-cell lymphoma that counts about 85% of annually cases.
- T-cell (15% of cases).

Another possible deviation is in indolent (slow-growing) and aggressive (fast growing).

There are 4 possible stages of the disease depending on its extension:

- I. Early Stage: Cancer is found in a single lymph, an organ or in an area outside the lymph node.
- II. Locally Advanced Disease: Cancer is found in two or more lymph node regions on the one side of the diaphragm.
- III. Advanced Disease: Cancer on this stage is found in lymph nodes on both sides of the diaphragm.
- IV. Widespread disease: Cancer is spread in several parts of one or more organs or tissues or it can be found in the liver, blood and bone marrow.

There are many treatment options depending on the stage of the disease, the age and health of the patient and prior therapies. Some options are the active

surveillance, also known as watchful waiting, chemotherapy, stem cell transplantation, radiation therapy or novel targeted agents.

In the present study, a reporting quality analysis of RCTs from 2011 until 2016 will be conducted regarding the treatment of NHL. The items of the revised CONSORT 2010 statement checklist will be used.

2. METHODS

2.1 DATA SOURCES AND RESEARCH STRATEGIES

The Pub Med database was used to search for studies on RCTs for NHL treatments from 1/1/2011 to 31/12/2016. The search criteria were “*treatment*” and “*non-hodgkin’s lymphoma*”. The filter of the article, the language and the species were “Randomized Control Trials”, “English” and “humans” respectively.

2.2 ELIGIBILITY OF STUDIES

A study is considered eligible for analysis when is in line with the following criteria. The participants have to be randomly assigned to at least two treatment arms. Patients should have any type of NHL and the aim of the study should be the treatment of NHL. RCTs about health quality, treatment of side effects or consolidation treatment were not included in the analysis. Moreover, studies comparing the results of previous publications were included only if these were RCTs.

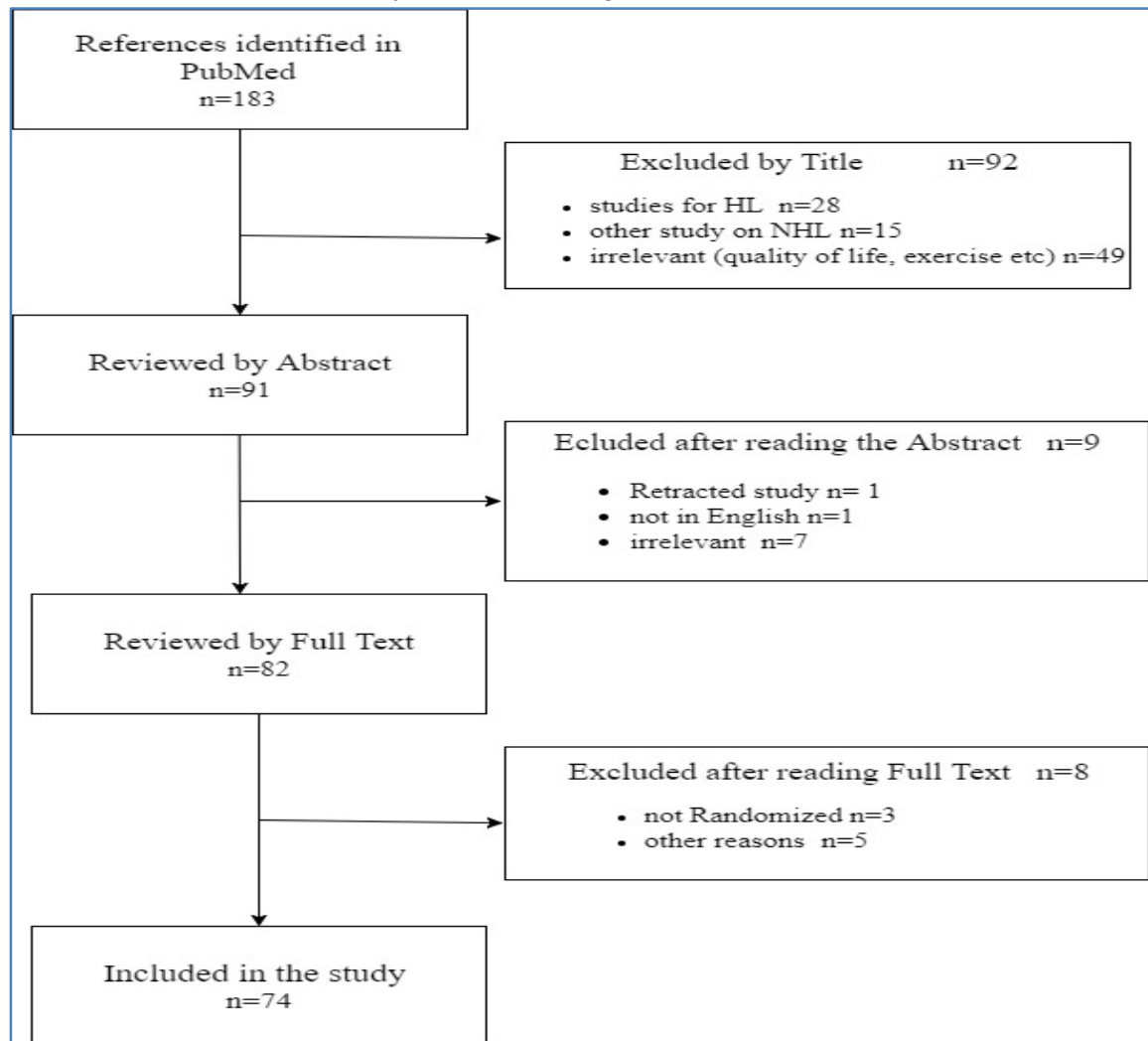
2.3 REPORTING ASSESSMENT TOOL AND EVALUATION ANALYSIS

The revised CONSORT 2010 checklist (<http://www.consort-statement.org>) was used as an assessment tool for the studies. We used the 22-item checklist and the answers were based on the CONSORT 2010 Explanation and Elaboration that is available online from the CONSORT statement web page.

The evaluation analysis is based on the number of CONSORT statement items that are reported on the study. For each of the items in the list only two possible answers were considered (positive or negative). If the item is reported and there is sufficient elaboration then I conclude that it is present and the answer is positive. On the other hand if an item is not mentioned, even if it is carried out in the trial, or there are no necessary details presented in the study, then the answer is negative. For example, the CONSORT item 7: “How sample size was determined”, in order to have a positive answer the study should include, apart from the number of the participants in each arm, details on how it was calculated such as estimated outcomes in each group, the type II error level, statistical power etc (CONSORT E&E). Moreover, it is essential each of these items to be reported on the specific part of the study as indicated by the CONSORT statement. For instance, Consort item 14 “Dates defining the periods of recruitment and follow-up” if mentioned in the Results the answer is positive. But if it is mentioned in the METHODS then it is considered non-reported in the study. Last but not least, items reported on Appendix or Supplementary Data were not taken into consideration. For the evaluation of the studies Microsoft-excel 2010 software was used.

3. **RESULTS**

The search on Pub Med database retrieved 183 studies. From these, 92 studies, out of the initial selected ones, were excluded after screening the titles due to their irrelevant subject (quality of life, exercise, Hodgkin's lymphoma etc). After reading the abstracts of the 93 remaining studies I had to exclude 9 studies, 1 was retracted, 1 was not in English and 7 were irrelevant to this topic. The remaining 82 studies were analytically reviewed and 8 studies were left out mainly because of no randomization or because they were not in English or access was not allowed.



Flow Chart of search strategy

Table 1 summarizes the percentage of each item in the analyzed studies. In general, we can conclude that the items in the Results part are more in line with the CONSORT statement comparing to the items in the Method part. This can indicate that researchers are more interested in presenting their conclusive results than trying illustrating the design of the trials.

Almost all the studies (72 out of 74, 97.3%) mentioned either on the title or in the abstract that it was a randomized trial or that the participants were randomized in treatment groups. As we expect all studies present sufficient scientific background references justifying the need for a new trial (100%) in the introduction.

Table 1. Percentage of compliance with CONSORT statement

	1. Randomized in title/abstract	97,30%	72
	2. Scientific background in introduction	100,00%	74
METHODS	3. Eligibility criteria for participants	91,89%	69
	4. Precise details of the interventions in each arm	90,54%	67
	5. Objectives	98,65%	73
	6. End-points	97,30%	72
	7. Sample size	71,62%	53
	8. Method of randomization (sequence generation)	50,00%	37
	9. Allocation concealment	13,51%	10
	10. Implementation of randomization	27,03%	20
	11. Blinding (masking)	9,46%	7
	12. Statistical methods	93,24%	69
RESULTS	13. Participant flow	70,27%	52
	14. a Recruitment	63,51%	47
	14.b Follow Up	79,73%	59
	15. Baseline data	94,59%	70
	16. Numbers analyzed	78,38%	58
	17.a Outcomes	100,00%	74
	17.b estimation	94,59%	70
	18. Ancillary analyses	70,27%	52
	19. Adverse events	85,14%	63
DISCUSSION	20. Interpretation	85,14%	63
	21. Generalisability	64,86%	48
	22. Overall evidence	66,22%	49

Also, they clearly separated the primary, of great importance, from the secondary endpoints of the study.

Intervention applied in each treatment arm was sufficiently described in 90.54% (67) of the studies. Furthermore, 93.24% of the studies presented extensive information on the selection criteria of the participants for the trial and some of them presented

also exclusion criteria. The same percentage of studies (93.24%) described the statistical methods that were used for the analysis and the comparison of the primary and secondary outcomes of the study.

On the contrary, only 53 out of 74 (71.64 %) studies sufficiently demonstrated how the sample size was calculated. All studies reported the needed number of participants in each group but not all of them presented the level of statistical significance, the type I and type II errors etc.

The items that gathered the lowest percentages were those describing the Randomization and Blinding strategy. Only 7 out of 74 studies were clear on which blinding procedure was used and on who was blinded. In most of the studies, authors did not clearly report which group was blinded or how this happened. Last but not least, only in half (50%, 37 out of 74) studies the method of randomization was explained. They may refer to the ratio that was used for the randomization process but no further details on how it was implemented and even less studies, only 10 out of 74 (9.46%) explained how the allocation concealment was secured.

CONSORT statement strongly recommends authors to include a participants' flow diagram that will visualize how participants are allocated in treatment groups, how many were eliminated and why, in each phase of the trial. From the 74 studies analyzed only 53 (70.27%) included a flow diagram in the results part while some of the remaining presented it in the Appendix or Supplementary Data. Even less were the studies that reported sufficient details on participants' recruitment (47(63.51%) out of 74) in the results section. Those provided clear details about the follow-up period were 59 out of 74 (79.73%). They stated either the specific date that the follow-up ended for all participants or specified the period that the follow-up lasted after the randomization of the participants.

In order to evaluate the results of a study and the significance of them, it is important the treatment groups to have similar baseline characteristics and the only difference should be the treatment. Knowing the characteristics of the groups would be necessary for clinicians to evaluate for which patients the treatment is suitable and also for the right interpretation of the results. Based on my evaluation, 94.59% of the studies analyzed included a detailed table that presented the Baseline demographic characteristics of the participants.

It is very important for the analysis to demonstrate information about the number of participants in each group and to present all changes that may occur due to loss of participants, wrong allocation or randomization of ineligible participants. Authors should be clear on what was the population of patients that was used for the analysis and this was clear only for 58 of the studies I analyzed and only 30 of them reported that the analysis followed the intention-to-treat strategy.

		Methods												Results							Discussion				
		1. Title/abstract	2. Introduction/Scientific background	3. Eligibility criteria	4. Intervention in each arm	5. Objectives	6. End-points	7. Sample size	8. Method of randomization	9. Allocation concealment	10. Implementation of randomization	11. Blinding (masking)	12. Statistical methods	13. Participant flow	14. a Recruitment	14.b Follow Up	15. Baseline data	16. Numbers analyzed	17.a Outcomes	17.b estimation	18. Ancillary analyses	19. Adverse events	20. Interpretation	21. Generalisability	22. Overall evidence
Alexander S. et al.	2014	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alnahhas et al.	2015	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗	✓	✗	✗	✓	✓	✓	✗	✓	✓	✓	✗
Asselin a et al.	2016	✓	✓	✓	✗	✓	✗	✗	✓	✗	✗	✗	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗
Bachy E. et al.	2013	✓	✓	✗	✓	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Bittenbring JT et al.	2014	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓	✓	✓	✓	✗	✓	✗	✗
Bozzoli et al.	2015	✓	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓
Cabanillas et al.	2012	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Cunningham et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Czuczman et al.	2012	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓
Czuczman et al.	2011	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✗	✓
Davies et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓
Delarue et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dreyling et al.	2016	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓
Fayad et al.	2015	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Federico M. et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Flinn et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓
Fridrik et al.	2016	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Furtado et al.	2015	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✗	✗	✗	✓	✓	✓	✓	✗	✓	✓	✓	✗
Gisselbrecht et al.	2012	✓	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
Glass et al.	2014	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Hainsworth et al.	2014	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗
Herbrecht	2013	✗	✓	✓	✗	✓	✓	✓	✓	✗	✗	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Hermine et al.	2016	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Herold et al.	2015	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Hertzberg et al.	2014	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
Hoskin et al	2014	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓
Hsiao at al.	2015	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✗
Jaeger et al.	2015	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Kahl et al.	2014	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓
Ketterer et al.	2012	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✗	✗	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
Kimby et al.	2015	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Kluin-Nelemans et al.	2012	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Kuruvilla et al.	2015	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Leblond et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Leonard et al.	2015	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✗	✗	✓	✗	✗
Lessin et al.	2013	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Levy et al.	2014	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗
Maziarz et al.	2011	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓	✓	✓	✗	✗	✗	✗	✗
McClanahan et al.	2012	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
Merli Francesco et al.	2012	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikkelsen et al.	2014	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗
Molina et al.	2014	✗	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Morschhauser et al.	2013	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✗	✗	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗
Morschhauser et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Offner et al.	2015	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Oki et al.	2013	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Pettengell et al.	2013	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Pettengell et al.	2012	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pfreundschuh et al.	2011	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Press et al.	2013	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Radford et al.	2013	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Recher et al.	2011	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ribrag et al.	2016	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ribrag et al.	2013	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗
Robak et al	2015	✓	✓	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rummel at al	2016	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

and treatment, (*Herbrecht et al., 2013*). As I have already stated, there seems to be a preference in reporting more details on the Results than the Methods for most of the authors. This may imply that they are more interested in presenting the results rather than explaining in details the design of their research.

The two major weaknesses of this study are the lack of any medical background studies and the fact that there was not a second reviewer for the evaluation. The approach was based on a more practical method. Initially, I tried to identify the items of the CONSORT statement in the studies and then to evaluate them. I used as a guideline the CONSORT 2010 Explanation and Elaboration. However, my incomplete knowledge in medical made it difficult sometimes to perform an evaluation for some of the items such as whether or not the authors gave sufficient information on the treatment that was followed in each treatment arm or if the description of the eligibility criteria was sufficient. On the other hand, this can lead to a more unbiased evaluation of a study.

Further research is needed in the evaluation of RCTs on treatment of NHL as well as in the contribution of the CONSORT statement regarding its attribution in improving the quality of the published studies.

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